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Applicants: Shiguang Yu *et al.*

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**For: Dietary Non-Essential Amino Acid
Tyrosine Regulates The Body Weight Of
Animals Through Regulating The
Animal Appetite Or Food Intake**

Examiner: Nabila G. Ebrahim

Art Unit: 1618

Confirmation No.: 3241

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REQUEST FOR RECONSIDERATION

This is Applicants' Reply in response to the final office action mailed August 24, 2009 (the "Action"). Applicants respectfully request reconsideration in light of the following remarks.

I. Introduction

Claims 5-14 and 37 and 39-41 are pending in this application. No amendments are made to the claims. Accordingly, no new matter is added, and applicants respectfully request reconsideration of the pending claims 5-14, 37, and 39-41.

II. The Telephone Interview of October 14, 2009

The undersigned representative of applicants greatly appreciates the courtesies extended during the telephone interview on October 14, 2009. The Examiner and the undersigned discussed the status of claim 26, now canceled, and to which group this claim should have been included in the restriction requirement set out in the Action dated April

12, 2007.¹ The Examiner informed the undersigned that claim 26 should have been included in Group II.

III. Finality is Improper

Applicants respectfully submit that the rejection of the pending claims² set out on pages 2-4 of the Action is a new rejection that was not necessitated by applicants' amendment. Applicants appreciate the explanation on page 2 of the Action preceding the rejection, in which the Examiner discusses removing the Gerth and Nagaoka references due to the cancellation of claim 38 (applicants do not agree, however, with the assessment of the scope of the claims). The rejection now states that the claims are unpatentable over Morris IN VIEW OF Kempen, whereas the rejection set out in the non-final Office Action dated January 6, 2009 alleged the claims were unpatentable over Morris OR Kempen in view of Gerth and Nagaoka. Accordingly, the present rejection is not simply the removal of secondary references to Gerth and Nagaoka, but rather is a completely new rejection relying on a combination of Morris and Kempen, a combination that has not been previously advanced during prosecution of the present application.

Applicants cancellation of claim 38 could not have necessitated this new combination, nor could any of the other amendments set out in applicants' response dated May 6, 2009. Indeed, it appears that the new rejection in which Morris is now combined with Kempen is due to applicants' arguments and not the amendments. Page 6 of the Action discusses applicants' prior arguments, and alleges that applicants' arguments regarding the amount of tyrosine used in Morris is rendered moot by the new combination of Morris and Kempen. Modifying a rejection based on applicants' arguments, and making the rejection final is improper. Applicants therefore respectfully submit that the finality of the present Action is premature, and consequently, applicants respectfully request that the Examiner withdraw the finality of the Action.

¹ The restriction requirement restricted the original claims into four groups of invention, but claim 26 was not included.

IV. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn

Applicants greatly appreciate the Examiner's withdrawal of the rejections under 35 U.S.C. §102(b), as noted on page 2 of the Action. The Action continues to reject the pending claims, however, as allegedly obvious over certain documents. These rejections will be addressed in turn below.

Claims 1-14, 37, and 38 are rejected on pages 3-5 of the office action under 35 U.S.C. § 103(a) as obvious over Morris, *et al.*, U.S. Patent Application Publication No. 2001/001442 ("Morris") in view of Kempen, U.S. Patent No. 6,004,614 (Kempen"). Based on the Examiner's comments on pages 2-4 of the Action, applicants assume the Examiner intended to reject claims 5-14, 37, 39, and 40. Applicants respectfully traverse this rejection.

The U.S. Supreme Court analyzed the test for obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). "There is no necessary inconsistency between the [teaching, suggestion, motivation] test and the Graham analysis. But a court errs where it transforms general principle into a rigid rule limiting the obviousness inquiry." *Id.* The Supreme Court's analysis in *KSR* relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. *See Takeda*, 492 F.3d at 1357. Third, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions," *KSR* 127 S. Ct. at 1742. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008), the Federal Circuit further explained that this "easily traversed, small and finite number

² Applicants note that the rejection on pages 2-4 of the Action lists claims 1-14, 37, and 38 as the rejected claims. Applicants have canceled some of these claims in its most recent response. Accordingly, applicants

of alternatives . . . might support an inference of obviousness.” However, to the extent an art is unpredictable, as the chemical arts often are, KSR’s focus on these “identified, predictable solutions” may present a difficult hurdle because potential solutions are less likely to be genuinely predictable. *Takeda Chemical Industries, LTD et al. v. Alphapharm PTY., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

The claims encompass, *inter alia*, compositions comprising on a dry matter basis (a) from 7% to 70% by weight of protein, (b) from 1% to 60% by weight of fat, (c) from 0 to 90% by weight of carbohydrate, (d) from 0 to 40% by weight of dietary fiber, (e) from 0 to 15% by weight of nutritional balancing agent, (f) 0.01% to 0.4% by weight of tyrosine, and (g) 0.1% to 3 % by weight of phenylalanine. The claimed compositions were found to induce body weight loss in animals through reducing food intake or increasing satiety. This claimed invention allows the appropriate concentration of tyrosine and phenylalanine without the previously reported negative effects.

The combination of Morris and Kempen does not provide the legally required teaching or suggestion of the claimed invention. Moreover, one of ordinary skill in the art would not have been motivated to combine or modify the teachings of the references to obtain the claimed invention.

Morris discloses a broad range of effective amounts of tyrosine and/or phenylalanine, including amounts of from about 0.05% by weight. It is clear from Morris’ disclosure, however, that Morris prefers amounts of amino acid above the upper limit (0.4%) recited in the present claims. *See, e.g.*, paragraphs [0023], [0024], [0026], [0027], [0034], [0035], and the examples of Morris. The Action admits that neither Morris nor Kempen expressly discloses the claimed range.

Morris also fails to disclose the remaining ingredients listed in the present claims in the recited amounts. The Action makes the factually unsupported allegation that “animal food ingredients such as proteins, carbohydrates, fats, and dietary fibers are conventional ingredients that are known to be used in different amounts and ranges.” *See* Action at 3. Even if true, the Action must either provide a reference that can be combined with Morris

assume the Action intends to reject 5-14, 37, 39 and 40.

that discloses these ingredients, or take official notice of the facts alleged. The Examiner has not provided a reference or taken official notice.³ Accordingly, the Action has failed to present a *prima facie* case of obviousness. Mere allegations are insufficient.

Kempen discloses the use of dicarboxylic acids, dicarboxylic acid metabolites, and their derivatives as animal feed ingredients. The Action relies on Kempen's disclosure in table 2 of the use of 0.15% tyrosine, and certain amounts of carbohydrate, protein, and fat containing ingredients. The Action thus concludes that "once a method of using an ingredient is known it is within the skill of the skilled artisan to determine the optimum amounts to use and the optimum end points in using the ingredient." Action at 3. The Action again recognizes that neither Morris nor Kempen disclose the precise amounts of ingredients recited in the claims, and concludes that "[o]ptimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art," and that it "would have been customary for an artisan of ordinary skill to determine the optimum amount of each ingredient such as protein, carbohydrate, dietary fibers, fats, tyrosine and phenylalanine." Action at 4. The Action finally notes that "absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicants' invention." *Id.*

Initially, there are exceptions to the general "obvious to optimize" principles set out in the Action. The Examiner has noted one of those exceptions – when the results obtained are unexpected. The other exception is when the variable modified (or allegedly "optimized") is not an art-recognized result-effective variable. See *In re Antonie*, 559 F.2d 618 (CCPA 1977), and MPEP §2144.05[R-5] II(B) ("A particular parameter must first be recognized as a result-effective variable. . . before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation."). The Action has not provided any evidence that the variables recited in the present claims are result-effective variables.

³ While this new rejection now relies on a combination of Morris with Kempen, the Action does not allege, nor can it, that Kempen discloses each of the ingredients recited in the claims, in the recited amounts.

Even if one could argue that the amount of tyrosine and phenylalanine is described in Morris as a result-effective variable, a person having ordinary skill in the art would have found it obvious only to optimize its use in the context of Morris' disclosure. That is, the amount would have only been varied to achieve an optimal hair color maintenance or restoration effect. And Morris clearly informs the person having ordinary skill in the art to use much more of the claimed amino acids than the amounts recited in the claims.

Assuming *arguendo* that the Action has established a *prima facie* case of obviousness, the examples in the specification provide results that are unexpected in light of the cited art. As discussed above, Morris preferably uses greater than 0.5%, and even more preferably uses more than 1.65% tyrosine. The specification states that the inventors found that changing the tyrosine concentration (i.e., by decreasing it to less than 0.4% or less) in pet foods induces body weight loss in animals through reducing food intake or increasing satiety (specification at para. [0005]). The examples state that pet foods containing as little as 0.5% of tyrosine permitted cats to consume enough energy to maintain their body weight (i.e., they would not lose weight by eating pet foods containing this much tyrosine, or more). *Id.* at para. [0052].

Study 2 in paragraph [0056] of the specification presents results showing that cats lost on average 7.2% of their initial body weight when fed food containing 0.35% tyrosine and 0.82% phenylalanine, whereas cats fed with food containing 2.7% tyrosine and 0.96% phenylalanine lost only 1% of their body fat. This result is truly surprising and unexpected in view of the cited art. Study 3 in paragraph [0057] provides similar unexpected results. Cats fed food containing 0.34% tyrosine and 0.89% phenylalanine lost on average 6.7% of their initial weight, whereas cats fed food containing 1.95% tyrosine and 0.80% phenylalanine lost on average 4.3% of their initial weight. The prior art fails to suggest that the amount of tyrosine or phenylalanine has any effect on body weight, and the primary reference to Morris specifically prefers the use of 1.65% or more of tyrosine. The superior weight loss achieved only when tyrosine is used in an amount below about 0.4% by weight therefore is an unexpected result in view of the prior art.

In sum, the combination of references do not disclose or suggest pet food compositions including protein, fat, carbohydrate, dietary fiber, nutritional balancing agent(s), tyrosine, and phenylalanine, much less these ingredients in the claimed amounts. The Action has not established a *prima facie* case of obviousness based on the combination of Morris and Kempen. Finally, even if a *prima facie* case of obviousness has been established, the unexpected results shown in the specification preclude concluding that the claims would have been obvious under 35 U.S.C. §103. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Action also rejects claim 40⁴ under 35 U.S.C. §103 as allegedly unpatentable over Morris in view of Kempen, and further in view of Arthur Maurice Mark, U.S. Patent No. 2,178,210 ("Mark"). The combination of Morris and Kempen fails to render obvious the independent claim upon which claim 41 depends, for the reasons noted above. Mark is relied upon solely for its alleged disclosure of obtaining tyrosine from corn gluten. Mark therefore cannot cure the deficiencies of Morris and Kempen discussed previously. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

⁴ Applicants assume the Examiner intended to reject claim 41, not claim 30, as claim 41 recites the source of the tyrosine.

V. Conclusion

For at least the reasons discussed above, Applicants believe that the claims are allowable. Further and favorable consideration is solicited. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

Date: October 26, 2009

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